IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

OTSUKA PHARMACEUTICAL CO., LTD., Plaintiff, v. INTAS PHARMACEUTICALS LIMITED, ACCORD HEALTHCARE, INC., and HETERO LABS LIMITED, Defendants	HONORABLE JEROME B. SIMANDLE Civil Action Nos. 14-6158 (JBS/KMW) 14-6890 (JBS/KMW) 14-7405 (JBS/KMW)
OTSUKA PHARMACEUTICAL CO., LTD., Plaintiff, v. AUROBINDO PHARMA LIMITED, AUROBINDO PHARMA USA, INC., and AUROLIFE PHARMA LLC, Defendants.	**MEMORANDUM OPINION REGARDING OTSUKA'S UNOPPOSED MOTION FOR THE ENTRY OF SUMMARY JUDGMENTS OF NONINFRINGEMENT ON THEIR '350 PATENT CLAIMS**
OTSUKA PHARMACEUTICAL CO., LTD., Plaintiff, v. ALEMBIC PHARMACEUTICALS LIMITED, Defendant.	

SIMANDLE, Chief Judge:

These related patent infringement actions under the Hatch-Waxman Act, 35 U.S.C. §§ 271, 281, concern Plaintiff Otsuka Pharmaceutical Co, Ltd.'s (hereinafter, "Otsuka") position that the abbreviated new drug applications (hereinafter, "ANDAs") of Intas Pharmaceuticals Limited, Accord Healthcare, Inc., Hetero Labs Limited (hereinafter, the "**Accord Defendants**"), Aurobindo Pharma Limited, Aurobindo Pharma USA, Inc., Aurolife Pharma LLC (hereinafter, the "**Aurobindo Defendants**"), and Alembic Pharmaceuticals Limited (hereinafter, the "**Alembic Defendant**" and collectively, "**the Standalone Defendants**") infringe the method of use patent associated with Otsuka's Abilify®

aripiprazole product, U.S. Patent No. 8,759,350 (hereinafter, "the '350 patent").[1]

On November 16, 2015, this Court construed the phrase "a/the pharmaceutical composition" / "in combination with," as it appears in asserted claims 1 through 18 of the '350 patent, to mean "a single dosage form, or 'pharmaceutical composition,' containing at least two active ingredients: aripiprazole and at least one of citalopram, escitalopram and salt thereof." Otsuka Pharm. Co. v. Torrent Pharm. Ltd., Inc., ___ F. Supp. 3d ____, 2015 WL 7195222, at *22 (D.N.J. Nov. 16, 2015) (hereinafter, the "Markman decision"). In view of this construction, and Defendants' representations concerning the single-ingredient nature of their ANDA products, Otsuka seeks the entry of summary judgment in favor of the Standalone Defendants on the '350 patent infringement claims.[2] [See Docket Item 136 in 14-6158;

[1] The standalone nature of these related actions makes them contextually different from the larger series of related cases involving Otsuka, including separate actions involving these Standalone Defendants, and not involving the '350 patent. See, e.g., Otsuka v. Accord, et al., No. 14-3996 (involving Otsuka's '615, '796, and '760 Patents); Otsuka v. Aurobindo, et al., No. 14-3306 (involving Otsuka's '615, '796, and '760 Patents); and Otsuka v. Alembic, No. 14-2982 (involving Otsuka's '615, '796, and '760 Patents).

[2] Assuming the entry of summary judgments of noninfringement, Otsuka then requests that Defendants' counterclaims concerning the '350 patent be dismissed without prejudice. This Court will, as explained below, enter summary judgments of noninfringement on the '350 patent. As a result, the Court will dismiss Defendants' counterclaims directed at the '350 Patent without prejudice to reinstatement in the event the Federal

Docket Item 114 in 14-6890; Docket Item 144 in 14-7405.] The Standalone Defendants acknowledge the propriety of summary judgment on the '350 patent claims, but seek to consolidate their standalone '350 patent cases with their related cases involving Otsuka's other aripiprazole Patents (in lieu of the entry of summary judgments), in order to avoid the distraction associated with Otsuka's intended appeal of this Court's Markman decision.[3] [See Docket Item 146 in 14-6158; Docket Item 124 in 14-6890; Docket Item 154 in 14-7405.]

For the brief reasons that follow, Otsuka's motions for summary judgment will be granted, and the Court will enter judgments of noninfringement in favor of the Standalone Defendants on the '350 patent.

The Court finds as follows:

1. **Factual Background**. For purposes of the pending motions, the Court need not retrace the lengthy factual and

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Circuit Court of Appeals reverses or remands this case back to this Court. See, e.g., Nystrom v. Trex Co., Inc., 339 F.3d 1347, 1351 (Fed. Cir. 2003) (citation omitted) (explaining the discretion of district courts "to dismiss a counterclaim ... as moot where [the court] finds no infringement").

[3] In light of the Standalone Defendants' request for consolidation, the Court afforded Otsuka an opportunity to voice its position on the issue. [See Docket Item 147 in 14-6158; Docket Item 125 in 14-6890; Docket Item 156 in 14-7405.] Otsuka, in turn, filed a response objecting to the Standalone Defendants' "attempted use of consolidation for the purpose of blocking Otsuka's appeal." [Docket item 148 in 14-6158; Docket Item 126 in 14-6890; Docket Item 159 in 14-7405.]

procedural background of these related infringement actions. Rather, it suffices to note that the Standalone Defendants have, since inception of these actions, taken the position that their proposed ANDA products cannot, as a matter of law, directly infringe any claim of the '350 patent, because their proposed aripiprazole products contain only a single active ingredient, aripiprazole, and not the multi-component pharmaceutical composition (consisting of aripiprazole in addition to either citalopram and/or escitalopram) disclosed by the '350 patent. [See, e.g., Docket Item 55 at 1 in 14-7405 ("Alembic's proposed generic product contains aripiprazole and only aripiprazole").]

2. In the Markman decision, this Court construed the phrases "a/the pharmaceutical composition" and "in combination with," as they appear in all asserted claims of the '350 patent, to mean "a single dosage form, or 'pharmaceutical composition,' containing at least two active ingredients: aripiprazole and at least one of citalopram, escitalopram and salt thereof." See Otsuka Pharm. Co., ___ F. Supp. 3d ____, 2015 WL 7195222, at *22. In other words, for a drug product to infringe the asserted claims of the '350 patent, as construed, that product must contain a single dosage form with two active pharmaceutical ingredients, aripiprazole and either citalopram or escitalopram, or salts thereof. Against that backdrop, the Court turns first to the Standalone Defendants' request for consolidation, and

then addresses Otsuka's principally unopposed position on summary judgment.

3. **Standard of Review Applicable to the Standalone Defendants' Consolidation Request**. Under Federal Rule of Civil Procedure 42(a),[4] "district courts have 'broad power' to consolidate cases that share 'common question[s] of law or fact.'" A.S. ex rel. Miller v. SmithKline Beecham Corp., 769 F.3d 204, 212 (3d Cir. 2014) (quoting Ellerman Lines, Ltd. v. Atl. & Gulf Stevedores, Inc., 339 F.2d 673, 675 (3d Cir. 1964), cert. denied, 382 U.S. 812 (1965); citing United States v. Schiff, 602 F.3d 152, 176 (3d Cir. 2010) (noting that a district court has "broad discretion in its rulings concerning case management")). The mere existence of common issues, however, does not require consolidation. See Liberty Lincoln Mercury, Inc. v. Ford Marketing Corp., 149 F.R.D. 65, 80-81 (D.N.J. 1993) (citations omitted). Nor can practical or administrative concerns serve, on their own, as a basis to consolidate. See ACR Energy Partners, LLC v. Polo N. Country Club, Inc., 309 F.R.D. 193, 194 (D.N.J. 2015) (citation omitted).

[4] Federal Rule of Civil Procedure 42(a) specifically provides that, "[i]f actions before the court involve a common question of law or fact, the court may: (1) join for hearing or trial any or all matters at issue in the actions; (2) consolidate the actions; (3) or issue any other orders to avoid unnecessary cost or delay." FED. R. CIV. P. 42(a)(1)-(3).

4. **Discussion**. Here, although these related actions, standalone or otherwise,[5] arise from the Standalone Defendants' ANDAs, and therefore share some common questions of law and/or fact with their other pending actions, the Court finds that consolidation would, at this time, be inappropriate. Indeed, given the parties' essential agreement that no litigable issues remain relative to the '350 patent, consolidation would primarily serve the impermissible purpose of impeding Otsuka's right to seek appellate review of this Court's Markman decision until after the other patent claims are resolved in the related actions.[6] For that reason, this Court declines to exercise its discretion to consolidate these actions with the Standalone Defendants' other aripiprazole patent cases not involving the '350 patent.

5. **Standard of Review Applicable to Otsuka's Summary Judgment Motion**. Under Federal Rule of Civil Procedure 56(a), summary judgment is appropriate if "there is no genuine issue as to any material fact and the moving party is entitled to

[5] The related separate actions involving these same Standalone Defendants but not containing claims based on the '350 patent are identified in note 1, supra.

[6] The Court recognizes that an appeal will invariably distract counsel, to some extent, from their active aripiprazole litigation in this District. Nevertheless, the practical difficulties of an appeal do not provide a basis for consolidation, particularly where consolidation would, in effect, delay Otsuka's opportunity for appellate review.

judgment as a matter of law." Alabama v. North Carolina, 560 U.S. 330, 344 (2010) (citations and internal quotation marks omitted); see also FED. R. CIV. P. 56(a). In other words, where "the record taken as a whole could not lead a rational trier of fact to find for the non-moving party," the Court may grant summary judgment. Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp., 475 U.S. 574, 587 (1986).

6. **Discussion**. This Court's Markman decision construed the asserted claims of the '350 Patent, as explained above, to claim a product comprised of a single dosage form with two active pharmaceutical ingredients, aripiprazole and either citalopram or escitalopram, or salts thereof. See Otsuka Pharm. Co., ___ F. Supp. 3d ____, 2015 WL 7195222, at *22. In these cases, though, there is no genuine factual dispute that the Standalone Defendants' ANDA products contain only a single active ingredient, aripiprazole, and not the two active pharmaceutical ingredients required by the '350 patent. As a result, there remains no triable issue on Otsuka's claims of infringement under the '350 patent. More specifically, the Court finds the Standalone Defendants' ANDA products noninfringing, because they do not contain the two active

ingredients required by the '350 patent, as construed in this Court's Markman decision.[7]

7. For all of these reasons, Otsuka's motions for summary judgments of noninfringement will be granted. Appropriate judgments of noninfringement, largely in the form proposed by Otsuka, will be entered in each action.

March 30, 2016
Date

s/ Jerome B. Simandle
JEROME B. SIMANDLE
Chief U.S. District Judge

[7] The Court finds it noteworthy that stipulated judgments of noninfringement have been entered in every related case involving the '350 patent (all of which concern generic defendants that equally claim single-ingredient aripiprazole products). [See, e.g., Docket Item 206 in 14-3168; Docket Item 143 in 14-4508; Docket Item 201 in 14-4671; Docket Item 155 in 14-5537; Docket Item 156 in 14-5876; Docket Item 209 in 14-5878; Docket Item 208 in 14-6398; Docket Item 131 in 14-7105; Docket Item 164 in 14-7252; Docket Item 225 in 14-8074; Docket Item 119 in 14-8077; Docket Item 116 in 15-1585; Docket Item 146 in 15-161.]